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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,775	09/15/2003	Andrea Marinello	930071-2001	2185
20/999 7590 11/13/2008 FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151				
EXAMINER				
GHALL, ISIS A D				
ART UNIT		PAPER NUMBER		
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11/13/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/662,775

Applicant(s)

MARINELLO ET AL.

Examiner

Isis A. Ghali

Art Unit

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 and 31-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged of applicants' request for reconsideration filed 08/04/20087.

Claims 1-33 are pending

Claims 1-12 and 31-33 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/06/2006.

Claims 13-30 are included in the prosecution.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

Art Unit: 1611

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 13, 15-25, 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2,262,711 ('711) in view of US 4,193,401 ('401).

US '711 teaches medical nebulizer used for treating sinusitis (col.1, lines 1-5). The nebulizer comprises mask, medicament in a chamber, and pressure provided by motor to vaporize the medicine to small pores of the sinus tract (col.1, lines 13-39). The medicaments are contained in a sponge member (col.3, lines 21-23).

Therefore, delivering medicaments to the sinuses derived by pressure force using face mask is known in the art.

Although US '711 suggests pressure to deliver of the medication, however, it does not teach the inflatable pad as required by claims 13 and 25, or means to secure the mask to the person's head as claimed in claims 20 and 29. US '711 does not explicitly teach delivering medicament to the underlying tissue, however, such function is implied and depends on if the formulation of the medicament administered is capable to penetrate skin or not.

US '401 teaches mask to deliver medicament to the underlying tissues, the mask comprises medicament impregnated in a pad and delivered by force of inflatable elastic pump in order to concentrate the medicaments and inject them as near as possible to the injured or inflamed part (abstract; col.2, lines 55-61, col.3, lines 24-28, 39-40; figure 1). Figure 3 shows the mask is supplied by strips to affix the mask to the patient's head. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide device comprising mask, medicament contained in a sponge member, and pressure to deliver the medicine to the sinuses as disclosed by US '711, and use the inflatable elastic pump to deliver the medicaments from the sponge member as disclosed by US '401, motivated by the of US '401 that such a pressure elastic pump concentrates the medicaments and injects them as near as possible to the injured or inflamed part, with reasonable expectation of having device comprising mask, medicament contained in a sponge member, and elastic pump to deliver the medicine as near as possible to the injured or inflamed part including sinuses with great success. Additionally, one having ordinary skill in the art would have added the strips used to affix the mask disclosed by US '401 to the mask of US '711 motivated by the teaching of US '401 that such strips secure the device to the head of user, with reasonable expectation of having device comprising mask that has strips to secure the mask to the face of the user. Therefore, the claimed invention as whole is taught and obvious in view of the combination of the cited art. It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is

Art Unit: 1611

obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions."

Response to Arguments

4. Applicant's arguments filed 08/04/2008 have been fully considered but they are not persuasive.

Applicants argue that US '711 teaches introducing volatilized medicaments to the respiratory system (nebulizer) and does not suggest the urge of active ingredients through the pores of the skin to reach the bones underlying mucous membranes below the skin. US '711 does not teach the sponge as a component of the mask or the described embodiment allows unobstructed respiratory function of the nostril. Applicants argue that the active agent in the present invention is soaked in water at 10°C (50°F) rather than heating taught by US '711. US '401 fails to cure the deficiencies of US '711 as it is directed to an apparatus applicable to the external part of the orbital cavity to introduce medicaments for the cure of internal injuries, wounds, or inflammation to the ocular organs and the central nervous system, and not to the underlying bones in the sinuses. There is no suggestion or motivation to modify the reference or to combine reference teachings either in the references themselves or in the general knowledge available to one of ordinary skill in the art; and there is no reasonable expectation of

Art Unit: 1611

success. The combination of US '711 and US '401 fails to teach or suggest all of the instant claim limitations, specifically the absorption of the active ingredients to bones underlying mucous membranes in a sinus of the wearer.

In response to these argument, applicants' attention are directed to the scope of claim 13 that is directed to device, and claim 25 that is directed to method of its use, and all the elements of the device are disclosed by the combined teaching of the references. The method claim 25 requires one step of securing the device to the person's head which also disclosed by the references. US '711 is directed to treating sinuses. At col.1, lines 36-39, US '711 teaches that the medicament penetrates the small pores of the sinus tracts, as required by the present device and method. The claims included in the rejection do not exclude volatilized medicaments. Regarding heating, US '711 is silent regarding the heating temperature, and the temperature does not impart patentability to the claims, absent evidence to the contrary. US '401 is relied upon for the solely teaching delivering of medicament impregnated in a pad by force of inflatable elastic pump to the injured or inflamed part, and also for teaching means for securing the device to the head. The test for obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). US '711 and US '401 are analogous art and both directed to delivery of medicament from device mounted to the head to the underlying bone, their combination is proper.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide device comprising mask, medicament contained in a sponge member, and pressure to deliver the medicine to the sinuses as disclosed by US '711, and use the inflatable elastic pump to deliver the medicaments from the sponge member as disclosed by US '401, motivated by the of US '401 that such a pressure elastic pump concentrates the medicaments and injects them as near as possible to the injured or inflamed part, with reasonable expectation of having device comprising mask, medicament contained in a sponge member, and elastic pump to deliver the medicine as near as possible to the injured or inflamed part including sinuses with great success. Additionally, one having ordinary skill in the art would have added the strips used to affix the mask disclosed by US '401 to the mask of US '711 motivated by the teaching of US '401 that such strips secure the device to the head of user, with reasonable expectation of having device comprising mask that has strips to secure the mask to the face of the user. Therefore, the claimed invention as whole is taught and obvious in view of the combination of the cited art.

It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions."

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a) as the invention as a whole is taught by the combined teaching of the references.

5. Claims 14 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '711 in view of US '401, and further in view of US 5,248,504 ('504).

The combined teachings of US '711 and US '401 are discussed above. However, the combined teachings of the references do not teach allyl isothiocyanate as an active ingredient to be delivered to the sinuses as claimed by claims 14 and 26.

US '504 teaches method for treating nasal sinuses dysfunction comprising applying allyl isothiocyanate to the affected mucosa by spraying (abstract; col.2, lines 20-22, 35-39, 50-52).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide device comprising mask, medicament contained in a sponge member, and elastic pump to deliver the medicine as near as possible to the injured or inflamed sinuses as disclosed by the combined teachings of US '711 and US '401, and replace the medicament by allyl isothiocyanate disclosed by US '504, motivated by the teaching of US '504 that allyl isothiocyanate treats nasal sinuses dysfunction when applied to the affected mucosa, with reasonable expectation of having device comprising mask, allyl isothiocyanate contained in a sponge member, and elastic pump that treats nasal sinuses dysfunction with great success.

Response to Arguments

6. With regard to the rejection of the claims 14 and 26 under 35 U.S.C. 103(a) as being unpatentable over US '711 in view of US '401, and further in view of US 5,248,504 ('504), applicant has failed to traverse the rejection and the response is considered to be acquiescence to the position taken by the examiner. The rejection is therefore repeated for reasons of record. See MPEP 37 CFR 1.111 (b).

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1611

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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